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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,839	09/30/2004	Kazuhiro Fukunaga	732964-55670	4338

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,839	Applicant(s) FUKUNAGA ET AL.	
	Examiner Abigail M. Cotton	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment submitted on December 14, 2005. Claims 9-24 are pending in the application, with claims 18-24 having been newly added. Accordingly, claims 9-24 are being examined on the merits herein.

The rejection of claims 9-17 under 35 U.S.C. 112, first paragraph, as lacking enablement for the prevention of periodontal disease is withdrawn in view of Applicant's amendment to remove the term "preventing" from claim 9.

The rejection of claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by EP 0 267 015 to Amy L. Finkenaar is being withdrawn in view of the cancellation of these claims. The rejection of claims 2-3 and 5-8 under 35 U.S.C. 103(a) as being obvious over Finkenaar is also withdrawn in view of the cancellation of these claims.

Applicant's arguments filed December 14, 2005 regarding the rejections of claims 9-17 under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,046,164 to Asano et al. in view of Finkenaar have been fully considered but they are not persuasive. Accordingly, these rejections are being maintained, and rejections over the newly presented claims 18-24 are being made.

Claim Objections

Claim 24 is objected to because the phrase "has a viscosity" has been mistakenly typed as "ahs viscosity." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,046,164 to Asano et al, issued April 4, 2000, in view of EP 0 267 015 to Amy L. Finkenaur, published May 11, 1988.

Asano et al. teaches a method for treating diseases of periodontal tissue by administering a basic fibroblast growth factor (see abstract, in particular.) Asano et al. teaches that the bFGF can be prepared in various formulations, including liquids by combining bFGF with a pharmacologically acceptable additive, such as a solvent, stabilizer, etc. (see column 4, lines 4-15, in particular.)

Asano et al. does not specifically teach providing a thickener in the bFGF composition.

Finkenaur teaches that a stabilizing effective amount of a water-soluble polysaccharide can be provided in medicinal compositions containing a polypeptide growth factor with mitogenic activity to stabilize the polypeptide growth factor against loss of biological activity in the presence of moisture (see abstract, in particular.) Finkenaur teaches that basic fibroblast growth factor is an example of such as polypeptide growth factor that can be stabilized with the polysaccharide (see page 3, lines 25-30, in particular.) Finkenaur further teaches that the polysaccharides act to increase the viscosity of the composition (see page 4, lines 55-65, in particular), and thus are thickeners.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate the stabilizer/thickener of Finkenaur into the bFGF composition taught by Asano et al. and administer for the treatment of periodontal disease, because Asano et al. teaches that a composition comprising bFGF and a stabilizer can be administered for the treatment of periodontal disease, and Finkenaur teaches that polysaccharides (that are also thickeners) act to stabilize bFGF. Thus, one of ordinary skill in the art would have been motivated to provide the polysaccharide of Asano et al. in the bFGF composition of Asano et al. for administration with the expectation of administering a stabilized formulation capable of treating periodontal

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disease. Therefore, the method of claim 9 is obvious over the teachings of Finkenaar and Asano et al.

Regarding claims 10-11, Finkenaar teaches that the stabilizing polysaccharide for stabilizing the polypeptide growth factor can be selected from among polysaccharides including methyl cellulose, hydroxyethylcellulose and hydroxypropyl methylcellulose, as in claim 10, and hydroxypropyl cellulose, as in claim 11 (see page 3, lines 35-50, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide one of the polysaccharides taught by Finkenaar in the bFGF composition of Asano et al. to form and administer the composition of claim 10 or 11, with the expectation of providing a polysaccharide-stabilized composition of bFGF capable of treating periodontal disease.

Regarding claims 12 and 15, Asano et al. teaches that the bFGF composition can treat periodontitis (periodontosis.) Regarding claims 13-14 and 16, Asano et al. teaches that a suitable content of bFGF in the composition can be from 0.001 to 20%, which is the same as the ranges being claimed. Regarding claim 17, Asano et al. teaches that the composition can be administered for repair of periodontal tissue after tooth extraction, and for regeneration of dentin defected by dental caries, as recited in the claim.

Regarding claims 18-19, Asano et al. teaches that the bFGF can be combined with pharmacologically acceptable additives, such as a suspending agent, stabilizer or filling material (see column 4, lines 1-13, in particular), and thus teaches that an inactive and non-toxic additive can be provided. Asano et al. also teaches that the bFGF can be combined with a solvent, and the composition can be prepared by a known method such as dissolution of the bFGF. Finkenaur teaches providing a polysaccharide (thickener) in the composition, as discussed above. Accordingly, the references teach providing the preparation in a solution for dissolution with a thickener and an inactive and non-toxic additive as recited in the claims.

Regarding claims 20-21, Finkenaur teaches the stabilized compositions can be in the form of aqueous medicinal compositions (see page 3, lines 55-60, in particular.)

Regarding the viscosity of the preparation as recited in claims 22-24, it is noted that Finkenaur teaches that the polysaccharide stabilizer can be provided to give a desired viscosity, such as a viscosity in the range of 1-5000 cps (see page 4, lines 55-65, in particular), which overlaps and/or encompasses that claimed. Finkenaur teaches that the increased viscosity improves the residence time of the effective concentration of the growth factor (see page 4, lines 55-64, in particular.) Finkenaur also generally teaches that the amount of cellulose derivative provided can be selected according to the concentration of the growth factor, the type of formulation and the like (see page 3, lines 55-62, in particular.) Accordingly, it is considered that one of ordinary skill in the

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art at the time the invention was made would have found it obvious to vary and/or optimize the amount and/or type of the cellulose derivative stabilizing agent provided in the composition, according to the guidance provided by Asano et al. and Finkenaur, to provide a composition having desired stabilization, viscosity and residence time properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Response to Arguments

Applicant's arguments filed December 14, 2005 regarding the rejections of claims 9-17 under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,046,164 to Asano et al. in view of Finkenaur have been fully considered but they are not persuasive.

In particular, Applicants argue that the references do not teach or suggest providing a viscous preparation, as claimed. The Examiner respectfully disagrees, as Finkenaur clearly teaches providing a cellulose derivative as a stabilizer that is also a viscosity increasing agent, and furthermore teaches that the cellulose derivative type and amount can be selected to provide the desired viscosity of the composition, and teaches that higher viscosity increases the residence time of the preparation, as discussed above. Accordingly, a method of treating by administering the composition

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as claimed is considered to be obvious over the teachings of Asano et al. and Finkenaur.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

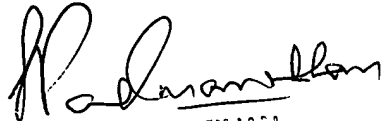
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC


SREENIVASAN PADMANABHAN
SUPERVISORY PATENT EXAMINER